DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 16, 2015

OBMedical Company
% Paul Dryden
Regulatory Consultant
ProMedic, Inc.
107 SW 140th Terrace, Suite 1
Newberry, FL 32669

Re: K142583
Trade/Device Name: LaborView LV1000
Regulation Number: 21 CFR 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: Class II
Product Codes: OSP, HGM
Dated: December 17, 2014
Received: December 18, 2014

Dear Paul Dryden,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K142583

Device Name

LaborView LV1000

Indications for Use *(Describe)*

The LaborView LV1000™ Wireless Electrode System is a transabdominal electromyography and electrocardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitors to measure fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). It is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies. It is intended for use by a healthcare professional in a clinical setting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date Prepared: 12-Jan-15

OBMedical Company
107 SW 140th Terrace, Suite 1
Newberry, FL 32669
Tel – 352.225.3682

Official Contact: Suha Jhaveri, COO

Proprietary or Trade Name: LaborView LV1000

Common/Usual Name: External uterine contraction monitor

Classification Name: OSP - uterine electromyographic monitor (CFR 884.2720)
HGM – Perinatal monitoring system (CFR 884.2740)

Predicate Devices: K112390 – Monica Healthcare – AN24

Device Description:
The LaborView LV1000 is a uterine activity and maternal and fetal heart rate sensor replacement intended to interface to existing perinatal monitors in use in hospital delivery environments.

LaborView is comprised of an electrode array, a wireless front-end ("**Front-end**"), computational back-end ("**Back-end**"), a power supply module, and optional adapters to connect to various perinatal monitors. The electrode array is sensitive to changes in electrical characteristics of the skin due to muscle contractions, maternal, and fetal ECG when placed on the expectant mother's abdomen. These signals are passed to LaborView, converted to a contraction curve and maternal heart rate (MHR), and fetal heart rate (FHR), and subsequently passed to the perinatal monitor. Note not all perinatal monitors support input of the MHR.

LaborView includes the hardware and firmware necessary to convert the electrical signals obtained via the electrode array into contraction, MHR, and FHR curves.

LaborView provides analog interfaces to the electrode array and the perinatal monitor but may also interface via USB to a data collection application running on a host PC.

The **Front-end** mates to the electrode array, digitizes the signals and transmits the signals wirelessly to the **Back-end** component. The **Back-end** receives the signals from the **Front-end**, implements the digital signal processing to create the MHR, FHR and contraction curves, then transmits them via the monitor cable/interface to the existing perinatal monitor.

A variety of connector adapters may exist between the **Back-end** and the perinatal monitor such that a single **Back-end** design can interface to a variety of perinatal monitor manufacturers and models.

The LaborView system power is supplied via an isolated power supply or a rechargeable battery pack.

All of the components of LaborView work together with the perinatal monitor to complete a system that can detect maternal contractions, MHR and FHR during labor. The perinatal monitor, in turn, may interface to a central monitoring system in order to conveniently present contraction information to clinicians.

Indications for Use:
LaborView LV1000 Wireless Electrode System is a transabdominal electromyography and electrocardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitors to measure fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). It is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies. It is intended for use by a healthcare professional in a clinical setting.

Patient Population:
Women (>36 completed weeks of gestation) in labor, with singleton pregnancies.

Contraindications:
LaborView is contraindicated for use in preterm gestation (<36 completed weeks).

LaborView may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. In the context of a preterm pregnancy, clinical misinterpretation of the uterine tracing may lead to unnecessary intervention, such as tocolysis, diagnostic procedures, and/or preterm delivery.

Environments of Use:
Hospitals, clinics, and doctors' offices

510(k) Summary

12-Jan-15

Table 5.1 - Table of the Similarities and Differences of Predicate vs. Proposed Device

	Predicate **Monica AN24 (K112390)**	**Proposed device** **LaborView LV1000**
Indications for Use	The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR), uterine activity (UA), and maternal heart rate (MHR). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN 24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG).	The LaborView LV1000™ Wireless Electrode System is a transabdominal electromyography and electrocardiography intrapartum maternal-fetal sensor. It works non-invasively via surface electrodes on the maternal abdomen with appropriate monitors to measure fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR). It is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies. It is intended for use by a healthcare professional in a clinical setting.
Patient population	It is intended for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen	It is intended for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen
Prescriptive	Trained medical personnel	Trained medical personnel
Environments of use	Clinical settings	Clinical settings
Data collected from sensor array	Uterine Activity (UA) Fetal Heart rate (FHR) Maternal Heart rate (MHR)	Uterine Activity (UA) Fetal Heart rate (FHR) Maternal Heart rate (MHR)
Components of the "system"	Electrodes placed on abdomen Cable Monitor to process and display data	Electrodes placed on abdomen (an array) Front-end wirelessly transmit data to receiver Back-end receiver connects to cleared perinatal monitor Monitor to process and display data* * The LaborView does not include the perinatal monitor
Technology employed	Transabdominal electromyography and electrocardiography signals	Transabdominal electromyography and electrocardiography signals
Information displayed	On graphical monitor	On graphical monitor* *Labor View is utilizing the existing monitor to display the information

510(k) Summary

12-Jan-15

	Predicate **Monica AN24 (K112390)**	**Proposed device** **LaborView LV1000**
Patient interface	Surface electrodes - Single patient use, disposable	Surface electrodes (array) - Single patient use, disposable
Contraindications	Contraindicated for use in preterm gestation (<36 completed weeks). May display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. In the context of a preterm pregnancy, clinical misinterpretation of the uterine tracing may lead to unnecessary intervention, such as tocolysis, diagnostic procedures, and/or preterm delivery.	Contraindicated for use in preterm gestation (<36 completed weeks). May display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. In the context of a preterm pregnancy, clinical misinterpretation of the uterine tracing may lead to unnecessary intervention, such as tocolysis, diagnostic procedures, and/or preterm delivery.
Clinical performance	Comparison to Tocodynamometer and IUPC for Uterine activity Comparison to pulse oximeter for Maternal Heart Rate	Comparison to Tocodynamometer and IUPC for Uterine activity Comparison to Fetal Scalp Electrode (FSE) for Fetal Heart Rate Maternal heart rate – ANSI / AAMI EC13 simulation
Biocompatibility ISO 10993-1	ISO 10993	ISO 10993-1 for patient contacting materials Surface Contact, Skin, Limited duration of use (<24 hours) Cytotoxicity, Sensitization, Irritation
Electrical / EMC / EMI	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-2-47	ANSI/AAMI/ES 60601-1 IEC 60601-1-2

Substantial Equivalence Discussion
The LaborView is viewed as substantially equivalent to the predicate devices because:

Indications –

- The LaborView is indicated for as a transabdominal electromyography (EMG) monitor intended to measure intrapartum uterine activity (UA), Fetal heart rate (FHR), and Maternal heart rate (MHR).
- **Discussion** – This is identical to the predicate K112390 – Monica AN2.

Patient Population –

- It is intended for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen
- **Discussion** – The patient population is identical to the predicate - K112390 – Monica AN24.

Environment of Use –

- For use in clinical settings by trained medical personnel
- **Discussion** – The environments of use and personal are identical to the predicate K112390 – Monica AN24.

Technology –

- The use of transabdominal electromyography (EMG) signals to sense uterine activity, fetal heart rate, and maternal heart rate via an array of surface electrodes placed on the maternal abdomen.
- The LaborView is only a sensor that sensing and transmits the signals to a standard perinatal monitor. It utilizes the existing GE Corometrics perinatal monitors for display and alarm functionality.
- **Discussion** – This technology is identical to the predicate K112390 – Monica AN24. The difference is that the LaborView is connected to a standard perinatal monitor that displays the data and has alarms. The LaborView is replacing or supplementing ultrasound for FHR; pulse oximeter for MHR; and Toco for uterine activity (UA). The LaborView plus an existing perinatal monitor create a total system equivalent to the predicate. This configuration has been demonstrated to be substantially equivalent and any difference does not raise any new safety risks that could not be confirmed through verification and validation testing.

Non-clinical Testing Summary -

We have performed a number of tests appropriate for the proposed device. These tests include:

Biocompatibility of Materials –

- The only materials in contact with the patient are the electrodes. We have performed ISO 10993-1 testing as Surface Contact, Skin, Limited duration of use: cytotoxicity, sensitization, and irritation.
- **Discussion –** The materials have been found to be non-reactive per ISO 10993-1 testing.

Electrical, EMC, EMI testing –

- We have evaluated the proposed device per ANSI/AAMI/ES 60601-1 and IEC 60601-1-2, and Wireless Coexistence and the device performed as intended meeting the requirements.
- **Discussion –** The proposed device met the requirements of the standards and is considered safe.

Bench testing –

- Bench testing was performed to verify the performance to specifications of the proposed device. In addition, LaborView was tested to ANSI/AAMI EC13 for verification for Maternal Heart Rate (MHR).
- **Discussion –** The proposed device was tested to assure that it meets its performance specifications. Upon completion of the tests, it was found to meet its performance requirements.

Clinical Testing Summary -

Usability –

We performed a summative usability study with potential users. Participants used the instructions to complete a series of tasks to evaluate the sensor array placement, device feedback interpretation (i.e., what to do in the case of icons lighting up on the transmitter), and sensor array removal. All participants were able to complete all tasks successfully.

Comparative Clinical Testing –

Measurement of Uterine Activity

A prospective, non-randomized multi-center study enrolling intrapartum patients at term gestation in whom an intrauterine pressure catheter (IUPC) had been placed. Total enrollment was 107 subjects.

The purpose of the study was to evaluate the performance of the LaborView System in a series of term deliveries. The LaborView was compared to standard external sensors [tocodynamometer (Toco) for UA] relative to the gold standard internal sensors [IUPC].

Primary Endpoints:

- For interpretability, a positive percent agreement (PPA) was calculated for each patient. LaborView (or Toco) uterine activity vs. IUPC gold standard was organized into a 2x2 table representing interpretable and uninterpretable data. PPA was defined as the percent of 0.125 second epochs with interpretable IUPC (gold standard data) that are also interpretable by the LaborView or Toco.

- For sensitivity, the individual contractions identified by LaborView or toco and the IUPC gold standard vs. those detected only by the IUPC was tabulated. The proportion of contractions detected within +/- 30 seconds by LaborView or Toco was calculated.

- For timing accuracy, the difference in timing of corresponding contractions between the IUPC gold standard and the LaborView (or Toco) was calculated.

All three of the above endpoints were tested using non-inferiority hypotheses.

The results of the study indicated that the LaborView device performed as well as Toco for measuring uterine activity.

Substantial Equivalence Conclusion:

The sponsor has demonstrated through performance testing, design and features, non-clinical, and clinical testing that the proposed device has been found to substantially equivalent to the predicate device.